

Remarks

Claims 2-6 are in the present patent application and have been amended to be independent claims. Claim 9 was never in the application due to a numbering error. Claims 10-21 were canceled during a preliminary amendment. Claims 27 and 29 have been amended in response to a telephone conversation with the Examiner on August 1, 2006. Applicants hereby cancel Claims 1, 7-8, 22-26, 28, and 30-33 without prejudice and reserve the right to pursue the canceled subject matter in a later application. Applicants have amended the title of the invention in response to a request by the Examiner for a more descriptive title.

Applicants request reconsideration and allowance of Claims 2-6 in view of the following arguments.

Claim Objections

Claim 6 stands objected to under 37 CFR 1.75 as being a substantial duplicate of Claim 2. The Examiner alleges that these two claims are duplicates or else are so close in content that they both cover the same thing. Applicants respectfully traverse this objection.

Claim 2 claims a crystalline biphenyl-4-carboxylic acid (R)-(6-(1-((4-fluorobenzyl)methylamino)ethylideneamino)-2(R)-hydroxyindan-1-yl)amide hemihydrate with **at least one peak** at 5.2, 6.2, 12.6, 14.0, 15.6, 17.0, 18.8, 19.6, 20.0, **or** 22.6 ($\pm 0.1^\circ 2\theta$). Claim 6 claims a crystalline biphenyl-4-carboxylic acid (R)-(6-(1-((4-fluorobenzyl)methylamino)ethylideneamino)-2(R)-hydroxyindan-1-yl)amide hemihydrate **requiring all of the peaks** at 5.2, 6.2, 12.6, 14.0, 15.6, 17.0, 18.8, 19.6, 20.0, **and** 22.6 ($\pm 0.1^\circ 2\theta$) to be present. As such Claims 2 and 6 differ significantly in scope.

Applicants have a right to restate (i.e., by plural claiming) the invention in a reasonable number of ways. Indeed, a mere difference in scope between claims has been held to be enough. MPEP 706.03(k). As such, Claims 2 and 6 are different in scope and are not duplicative claims. Applicants respectfully request the removal of the objection to Claim 6.

Claims 2-6 and 8 stand objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the

base claim and any intervening claims. Applicants have amended Claims 2-6 to be independent claims and canceled claim 8 thereby obviating the objection. Applicants respectfully request the objection to Claims 2-6 be withdrawn and these claims be allowed.

Rejection of Claims 22-33 Under 35 USC §112, First Paragraph

Claims 22-33 stand rejected under 35 USC §112, first paragraph, as failing to comply with the written description requirement. The Examiner has alleged that while being enabled partially for the treatment of diseases associated with the muscarinic M-1 receptor, it does not enable one skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

While Applicants do not acquiesce to the merits of the present rejection, in order to further prosecution, Applicants have canceled Claims 22-26, 28, and 30-33 without prejudice thereby obviating this rejection as it relates to these claims. In a phone conversation with the Examiner on August 1, 2006, the Examiner indicated that the subject matter of Claims 27 and 29 would be allowable if the term, “prophylactically treating” was amended out of the claims. Applicants have made these amendments and believe that Claims 27 and 29 are now allowable and respectfully request the Examiner to withdraw the rejection as it relates to these claims.

Provisional Rejection of Claims 1, 7, and 22-33 under Non-Statutory Obviousness-Type Double Patenting

Claims 1, 7, and 22-33 stand provisionally rejected for non-statutory obviousness-type double patenting over Claims 12, 14, and 16-20 of United States Patent Application No. 10/488,519, now US PGPUB 20040242584 A1 (the ‘519 application”) in light of the teachings of *SmithKline Beecham Corp. v. Apotex Corp* (403 F.3d 1331, 1343-44 (Fed Cir. 2005)). The Examiner asserts that while the ‘519 application does not teach the hemihydrate form specifically, *SmithKline Beecham Corp. v. Apotex Corp.* states a claim to a compound, especially an anhydrous form, “inherently anticipates” the instantly claimed hemihydrate form because practicing the process to manufacture the anhydrous compound “inherently results in at least trace amounts of” the claimed hemihydrate even if the prior art did not discuss or recognize the hemihydrate.

Applicants have canceled Claims 1, 7, 22-26, 28, and 30-33 without prejudice thereby obviating this rejection as it relates to these claims. In a phone conversation with the Examiner on August 1, 2006, the Examiner indicated that the subject matter of Claims 27 and 29 would be allowable if the term, "prophylactically treating" was amended out of the claims. Applicants have made these amendments and believe that Claims 27 and 29 are now allowable and respectfully request the Examiner to withdraw the rejection as it relates to these claims.

In view of the foregoing, Applicants respectfully request the allowance and passage of issuance of Claims 2-6, 27, and 29. Please charge any fees, including the one-month extension, or credit any overpayment in connection with this application which may be required by this or any related paper to Deposit Account No. 05-0840.

If the Examiner has any questions, or would like to discuss any matters in connection with this application, he is invited to contact the undersigned at (317) 277-3537.

Respectfully submitted,

/Tina M. Tucker/

Tina M. Tucker
Attorney for Applicants
Registration No. 47,145
Phone: 317-277-3537

Eli Lilly and Company
Patent Division/TMT
Lilly Corporate Center
Indianapolis, Indiana 46285

August 11, 2006